UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC

EXHIBIT INDEX

PLAINTIFF'S RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS OF SUZANNE PARISIAN, M.D.

Exhibit 1	Declaration from Suzanne on her background
Exhibit 2	Parisian Deposition Excerpts 6-3-14
Exhibit 3	Parisian Deposition Excerpts 6-27-17
Exhibit 4	BPVEFILTER-01-01780607 (**FILED UNDER SEAL**)
Exhibit 5	SIR Guidelines

EXHIBIT 1

Ramon Rossi Lopez - rlopez@lopezmchugh.com
(California Bar Number 86361; admitted *pro hac vice*)
Lopez McHugh LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
949-812-5771

Mark S. O'Connor (011029) – mark.oconnor@gknet.com
Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
602-530-8000

Co-Lead/Liaison Counsel for Plaintiffs

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **DECLARATION OF SUZANNE PARISIAN, M.D.**

I, Suzanne Parisian, M.D. declare and state as follows:

1. I am over the age of 18 and the statements made below are true and correct of my own personal knowledge, unless otherwise stated.

2. From 1991 to 1995, I was a commissioned officer in the United States Public Health Service ("USPHS")—achieving a final rank of Lieutenant Commander—assigned to the FDA.

3. At the FDA, I worked in the Center for Devices and Radiological Health ("CDRH").

4. Part of my responsibilities at CDRH were to provide medical and regulatory support to members of the FDA for both pre-market and post-market issues.

5. From 1991-93 I was a member of the Office of Health Affairs ("OHA"), a CDRH office of clinicians supporting a non-clinical Center Director.

6. As part of my job responsibilities at OHA I was to provide medical and regulatory support to members of the Office of the Center Director, Office of Compliance, Office of Device Evaluation, Office of Regulatory Affairs, Office of General Counsel,

District Offices at the FDA. My responsibilities at OHA included conducting health hazard and health risk assessment; creating of FDA Safety Alerts; communicating with physicians and laypeople; forensic review of patient deaths with medical devices; reviewing of adverse event reports in FDA's databases as well as in the medical and scientific literature to identify safety trends; providing clinical support for FDA during mandatory recalls including reviewing internal corporate and manufacturing records to ensure compliance with the FDCA and implementing regulations as well as guidance on the impact on the public health; and reviewing product labeling, promotions, advertising, and corporate records to ensure compliance with the Food, Drug and Cosmetic Act ("FDCA"). Throughout all my responsibilities, the goal was for me to use my training and experience to make recommendations to FDA to ensure patient safety.

7. In this function, I was required by my Supervisor to become familiar with the FDCA and its implementing regulations for all medical and radiological products marketed with FDA's oversight.

8. I was also assigned by the FDA to participate directly as an official member of FDA with industry groups, review and provide comment on industry standards, interact with professional groups, and represent FDA with other government agencies, including the Department of Defense (DOD) and the National Institutes of Health (NIH).

9. In 1993, CDRH clinical staff was re-organized by the FDA's Commissioner.

10. OHA was disbanded as a support office within CDRH, and all clinical staff including myself were reassigned to the Office of Device Evaluation ("ODE") with an increased emphasis on involvement in pre-market review of new products.

11. During this transition period at CDRH, I was required to continue my post-market OHA functions including procedures used for health risk assessments and health hazards evaluations pursuant to 21 C.F.R. Part 7 and to provide support to the members of the Office of Compliance.

12. Upon arriving at ODE, I was quickly promoted to be one of two Chief Medical Officers. In my capacity as Chief Medical Officer, I was now required to train

medical officers and scientific reviewers on the agency's regulations, and oversight of all pre-market review processes including 510(k)s (21 C.F.R. § 807), Pre-market Approval Applications (21 C.F.R. § 814) and Investigational New Device Applications (21 C.F.R. § 812). I was also required to continue my own daily pre-market review and application evaluation and clinical support role for ODE. At this time, I was also named as the FDA's official contact with the Office of Complimentary Medicine at the National Institutes of Health (NIH).

13. In conducting and training others on these review processes I was involved with consideration of a manufacturer's proposed design and feasibility studies; evaluated clinical trials, patient data, patient protections, proposed labeling, medical and scientific literature, annual report requirements, and medical device reporting; and interacted directly with industry, scientists, healthcare providers, and patient groups.

14. I actively reviewed proposed Sponsor's clinical trials and pre-marketing applications for medical devices, and as a pathologist in ODE, reviewed pre-clinical and animal toxicology and biocompatibility data to propose methods to industry for product safety testing. I also provided clinical support to CDRH and other FDA Centers for combination products.

15. I was one of the first instructors at CDRH's new staff college, training FDA clinical reviewers on the FDA's requirements as well as issues to be considered by them in the evaluation of clinical data provided in industry's investigational and pre-marketing applications.

16. My responsibilities while at FDA always included the review of both mandatory and voluntary adverse event reports submitted to the FDA by health care providers, patients, and others in order to identify safety trends occurring in FDA-regulated products and protect the public.

17. In OHA I presided over 162 health risk assessments. In ODE I presided over an additional 100 assessments.

18. I advised others within the FDA about public health risk issues and made recommendations based on my training and experience regarding subsequent regulatory actions that should or may be undertaken by stakeholders or FDA to help protect the public welfare.

19. I received my Medical Doctorate (M.D.) from the University of South Florida and am currently licensed as a physician in Arizona.

20. I have clinical patient-care experience in general practice and emergency medicine. Since 1989 I have been board-certified in Anatomic and Clinical Pathology.

21. I also hold a Master's Degree in Biology from the University of Central Florida.

22. As stated above, while at the FDA, I was serving as a member of the USPHS. As part of my USPHS clinical duties outside the FDA, I worked as a pathologist one half-day per week at the Armed Forces Institute of Pathology's ("AFIP") Office of the Medical Examiner for the Armed Forces in Washington, D.C. In that AFIP post as a medical examiner, I performed final quality sign-out as to the cause of death for autopsies performed on military and government personnel. As a result of that role, I reported a series of unexpected patient deaths associated with drug-device combination issue which subsequently prompted a major safety response by the FDA.

23. I have over 26 years of experience and training in the FDA's regulations as well as knowledge of the Sponsor roles with products regulated by FDA including the development, manufacture, monitoring, and marketing of medical devices.

24. Both as a medical officer at the FDA and with my later FDA Regulatory consulting firm (since leaving the USPHS and FDA in 1995), I have remained actively engaged in FDA regulatory issues including its oversight of medical devices.

25. Throughout my career and using the methodology acquired during my work for the FDA, I have reviewed hundreds of pre-market applications for medical devices.

26. As an FDA regulatory expert, I have been directly involved with industry, including product design and production, creation of submissions to obtain approval or clearance from the FDA, and safety issues.

27. As a medical and regulatory expert, I have been required—whether for FDA, litigation, or industry support—to review the regulatory history, testing, and clinical data for drugs, biologics, and medical devices as described by the manufacturer in marketing applications and communications with the FDA and the public. That review included review of proposed draft and final labeling, marketing, scientific and medical literature.

28. After leaving the USPHS and FDA in 1995, I created a regulatory consulting firm initially in Virginia. I relocated the business to Phoenix, Arizona in 2004. I have been a guest lecturer and consultant to individuals, professional and patient groups, students, industry, and law firms regarding the FDA's regulations and oversight of products.

29. I am currently a member of the Maricopa County Medical Society, the Arizona Medical Association, and the Arizona BioIndustry Association. I am a member of the American Medical Association as well as the FDA Alumni Association and Regulatory Affairs Professionals (RAPS). For RAPS, I was an online instructor in its course on FDA and medical devices.

30. My consultation work has required that I remain current with the relevant changes occurring at the FDA for its oversight of products. That role would include familiarity with FDA's issuance of Guidances for industry and its own reviewers, Safety Alerts, Recalls, enforcement actions, special reports, public working groups, reclassification of devices as well as FDA's harmonization of requirements internationally.

31. I also must maintain awareness of changes in the FDA's authority from Congress through its passage of amendments to the FDCA and the impact of those

amendments on the FDA's and Sponsors' roles for marketing devices, biologics, and drugs.

32. In summary, I have over 39 years of medical experience including 26 years of direct hands-on experience with FDA regulatory issues, public safety, and particularly pre-market clearance and approval processes for medical devices.

33. In 2001, I published a textbook about the FDA, *FDA Inside and Out*, which has been used as a graduate student textbook in the Biomedical Ph.D. programs at Wayne State University and Colorado State University.

34. For the past twenty years, I have provided forensic regulatory litigation support for both plaintiffs and defendants.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

EXECUTED on this 27th day of September, 2017.

Suzanne Parisian, M.D.

6215817v1/26997-0001

EXHIBIT 2

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

MELANIE RACKLIFF, an individual,

Plaintiff,

No: CV2011-021206

v.

C.R. BARD, INC., et al.,

Defendants.

VIDEOTAPED DEPOSITION OF

SUZANNE PARISIAN, M.D.

June 13, 2014

9:04 a.m.

Snell & Wilmer

400 East Van Buren, 19th Floor

Phoenix, Arizona 85004

Marcella Daughtry, RPR, CR No. 50623

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

KEVIN PHILLIPS, an individual,

Plaintiff

vs.

C.R. BARD, INC., a foreign corporation, BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, and DOES 1 through 100 inclusive,

Defendants.

Case No. 3:12-cv-00344-RCJ-WGC

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

TINA BARKLEY and JEFFERY BARKLEY, individually and as husband and wife, No. CV2011-021250

Plaintiffs,

v.

C.R. BARD, INC., et al.,

Defendants.

INDEX TO EXHIBITS

EXHIBITS	DESCRIPTION	MARKED
For the Defendants:		
Exhibit #1	Notice of deposition	12
Exhibit #2	Notice of taking videotaped deposition	12
Exhibit #3	Amended notice of taking videotaped deposition	12
Exhibit #4	Expert report of Dr. Parisian in Rackliff case	15
Exhibit #5	Expert report of Dr. Parisian	15
Exhibit #6	Documents obtained for case subsequent to last report.	19
Exhibit #7	Curriculum vitae	33
Exhibit #8	Court testimony list	34
Exhibit #9	Invoices (Original retained by witness)	70
Exhibit #10	Agreement for expert witness services (Original retained by witness)	84
Exhibit #11	Documents acquired since supplemental report (Confidential - subject to protective order) (Original retained by witness)	87
Exhibit #12	Copied folder on Phillips (Original retained by witness)	131
Exhibit #13	Copied folder on Barkley (Original retained by witness)	131

INDEX TO EXHIBITS, CONT'D

* * *

APPEARANCES OF COUNSEL

For The Plaintiffs:

LOPEZ MCHUGH, LLP
MR. RAMON ROSSI LOPEZ
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
Rlopez@lopezmchugh.com

For the Defendants:

NELSON MULLINS RILEY & SCARBOROUGH, LLP
MR. RICHARD B. NORTH, JR.
201 17th Street NW, Suite 1700
Atlanta, Georgia 30363
Richard.north@nelsonmullins.com

And

SNELL & WILMER, L.L.P.
MS. SARA M. ATHEN
One Arizona Center
400 East Van Buren
Phoenix, Arizona 85004
Docket@swlaw.com

Also Present:

Sheila Modena, videographer

(Deposition Exhibit Nos. 1 through 4 were marked for identification.)

THE VIDEOGRAPHER: We are on the record, and the time is approximately 9:04 a.m. This is the beginning of disc one for the video deposition of Suzanne Parisian, M.D.

Would counsel please identify themselves and who they represent for the record.

MR. LOPEZ: Ramon Lopez, Lopez McHugh on behalf of the plaintiffs.

MR. NORTH: Richard North on behalf of C.R. Bard and Bard Peripheral Vascular, the defendants.

MS. ATHEN: Sara Athen on behalf of the defendants.

THE VIDEOGRAPHER: Would the court reporter please swear in the witness.

SUZANNE PARISIAN, M.D.,

called as a witness herein, having been first duly sworn by the shorthand reporter to speak the truth and nothing but the truth, was examined and testified as follows:

MR. NORTH: This will be the deposition of Dr. Suzanne Parisian taken for purposes of discovery

and all other purposes permitted under the Arizona Rules or the Federal Rules of Civil Procedure. Specifically it's being taken in three separate cases in which Mr. Lopez represents the plaintiff; that is the Barkley case, the Rackliff case and the Phillips case.

As usual, Mr. Lopez, I propose that all objections except as to the form of the question and the responsiveness of the answer be reserved until use of the depo.

MR. LOPEZ: You mean just don't object at all?

MR. NORTH: No.

MR. LOPEZ: I'll do my best. I mean, I will follow the rules.

MR. NORTH: Okay.

MR. LOPEZ: Is that the rule in Arizona, too, you can only say objection, form?

MS. ATHEN: Yes.

MR. LOPEZ: You can't say anything beyond that?

MS. ATHEN: Right.

MR. LOPEZ: Okay.

THE VIDEOGRAPHER: Would you please wear your mic. Thank you.

EXHIBIT 3

Deposition of:

Suzanne Parisian , M.D.

June 21, 2017

In the Matter of:

In Re: Bard IVC Filters Products Liability

Veritext Legal Solutions
1075 Peachtree St. NE , Suite 3625
Atlanta, GA, 30309
800.808.4958 | calendar-atl@veritext.com | 770.343.9696

A. No, no. But it doesn't matter at the FDA. You have to become an expert in what you're given to work with.

Q. You are not a cardiologist; correct?

A. That's correct. Again, the FDA would use me for cardiology-related things, but I'm not a cardiologist.

Q. And you're not a hematologist?

A. I'm not a hematologist, other than in pathology you have to know about hematology. But I'm not a hematologist.

Q. Dr. Parisian, am I correct that you have never designed a IVC filter?

A. Yes, you're correct.

Q. Have you ever designed an implantable medical device?

A. Yes, and I think I've testified about this before. It was a CNS shunt for brain pressure. I had to help design that for a clinical trial that was being run at Stanford.

Q. Was this during the time period that you were at the FDA?

A. No, no. This was after FDA. And this was a -- using a shunt in old -- old patients -- elderly patients to try to treat Alzheimer's disease.

Q. Approximately when would that have been?
A. It would have been in the '90s, after I left FDA, around '97, '98.
Q. And is the shunt the only implantable medical device that you've ever designed?
A. The only one that I've designed from the very beginning as to what to put in it, how to -- how to get it cleared by the FDA, how to get it used in clinical trials, yes, sir.
Q. And the shunt was cleared by FDA?
A. It was -- it was cleared for -- it -- for an IDE. I don't know what hap- -- ever happened to the status of it, but it was cleared to be in an IDE in patients.
And the FDA doesn't design medical devices; they review medical devices.
Q. Did you work with a manufacturer as far as the production of that product?
A. Actually, I worked with the members of Stanford, and so then we got a manufacturer to create the device to use for the clinical trial.
Q. Was this product ever commercially available?
A. I don't know. I lost track of what happened in terms of the clinical trials. I don't

think they treat Alzheimer's with a CNS shunt, so my hunch is that it wasn't.

Q. Did the product have a particular name?

A. Not that I know of.

Q. So if I wanted to go on to the FDA website and try and find the IDE for this shunt, what -- what would I look for?

A. I wouldn't go to the FDA's website, because IDEs are confidential. I might go to the medical literature. I might go to the Internet and look for treatment of Alzheimer's with a CNS shunt to get rid of beta amyloid. So -- but it won't be on the FDA's website.

Q. And as far as you know, that particular shunt never came out of its IDE status; is that right?

A. As far as I know. And it was -- the study was conducted at Stanford, so that might also help you.

Q. Do you know who you worked with at Stanford in regard to that shunt?

A. I don't remember who it is anymore.

Q. Doctor, you were at FDA from 1991 to 1995; is that right?

A. Yes, sir.

EXHIBIT 4
(Filed Under Seal)

EXHIBIT 5

STANDARDS OF PRACTICE

Quality Improvement Guidelines for the Performance of Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism

Drew M. Caplin, MD, Boris Nikolic, MD, MBA, Sanjeeva P. Kalva, MD, Suvranu Ganguli, MD, Wael E.A. Saad, MD, and Darryl A. Zuckerman, MD, for the Society of Interventional Radiology Standards of Practice Committee

ABBREVIATIONS

DVT = deep vein thrombosis, IVC = inferior vena cava, PE = pulmonary embolism

PREAMBLE

The membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from both the private and academic sectors of medicine. Generally Standards of Practice Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such they represent a valid broad expert constituency of the subject matter under consideration for standards production.

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document are available upon request from SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033.

METHODOLOGY

SIR produces its Standards of Practice documents using the following process. Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned dependent upon the magnitude of the project.

An in-depth literature search is performed by using electronic medical literature databases. Then, a critical review of peer-reviewed articles is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, rates, and thresholds.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members by using a Modified Delphi Consensus Method (Appendix A). For purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Revisions Subcommittee members of the Standards of Practice Committee, either by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Subcommittee, and appropriate revisions made to create the finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

INTRODUCTION

This guideline was revised by the American College of Radiology (ACR) in collaboration with SIR.

These guidelines are written to be used in quality improvement programs to assess inferior vena cava (IVC) filter placement procedures. The most important processes of care are (i) patient selection, (ii) performing the procedure, and (iii) monitoring the patient. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

Pulmonary embolism (PE) continues to be a major cause of morbidity and mortality in the United States. Estimates of the incidence of nonfatal PE range from 400,000 to 630,000 cases per year, and 50,000 to 200,000 fatalities per year are directly attributable to PE (1–4). The current preferred treatment for deep vein thrombosis (DVT) and PE is anticoagulation. However, as many as 20% of these patients will have recurrent PE despite adequate anticoagulation (3,5,6).

Interruption of the IVC for the prevention of PE was first performed in 1893 by using surgical ligation (7). Over the years, surgical interruption took many forms (ligation, plication, clipping, or stapling), but IVC thrombosis was a frequent complication after these procedures. Endovascular approaches to IVC interruption became a reality in 1967 after the introduction of the Mobin-Uddin filter (8).

Many devices have since been developed for endoluminal caval interruption, and currently several devices designed for permanent placements are commercially available in the United States. In addition to

From the Department of Radiology, Division of Interventional Radiology (D.M.C.), North Shore University Hospital, Manhasset, New York; Department of Radiology (B.N.), Albert Einstein Medical Center, Philadelphia, Pennsylvania; Department of Radiology (S.P.K., S.G.), Massachusetts General Hospital, Boston, Massachusetts; Department of Radiology (W.E.A.S.), University of Virginia Health System, Charlottesville, Virginia; and Mallinckrodt Institute of Radiology (D.A.Z.), Washington University School of Medicine, St. Louis, Missouri. Final revision received July 15, 2011 and accepted July 16, 2011. **Address correspondence to** D.M.C., c/o SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033; E-mail: dcaplin@nshs.edu

S.P.K. receives royalties from book publishers Amirsys and Elsevier. W.E.A.S. is a paid consultant for Boston Scientific (Natick, Massachusetts), has research funded by Siemens (Forchheim, Germany), and serves on the Speaker's Bureau for Atrium (Hudson, New Hampshire). None of the other authors have identified a conflict of interest

The initial version of this article first appeared in JVIR 2003; 14:S271–S275.

J Vasc Interv Radiol 2011; 22:1499–1506

DOI: 10.1016/j.jvir.2011.07.012

permanent IVC filters, retrievable IVC filters are also available. These filters can be left in place as a permanent implant but also can be removed when the indication for filter placement resolves. (Detailed information regarding each of these filters can be found in several reviews [9–23].) Selection of a device requires knowledge of the clinical settings in which filters are used, as well as an evaluation of the clot-trapping efficiency and structural integrity of the device, the occlusion rate of the IVC and access vein, the risk of filter movement and filter embolization, magnetic resonance (MR) imaging compatibility of the device, and the ease of placement.

Placement of a caval filter can be performed as an outpatient or inpatient procedure. Practically speaking, however, most filter placements will occur in the inpatient population because of ongoing medical therapy for acute thromboembolic disease or underlying illness.

The IVC should be assessed with imaging before placement of a filter, and the current preferred method is by vena cavography. Before filter selection and placement, the length and diameter of the infrarenal IVC should be assessed, the location and number of renal veins determined, IVC anomalies defined (eg, duplication), and intrinsic IVC disease such as preexisting thrombus or extrinsic compression excluded. If available, earlier imaging studies (eg, contrast-enhanced computed tomography [CT] or MR imaging of the abdomen) may be used to evaluate the anatomy of the IVC (ie, size, patency, and anatomic variants). The ideal location for filter placement for preventing lower-extremity and pelvic venous thromboembolism is the infrarenal IVC. The apex or superior aspect of any filtration device should be at or immediately inferior to the level of the renal veins according to the manufacturer's recommendations. In specific clinical circumstances, other target locations may be appropriate.

Placement of a caval filter is commonly accomplished through right femoral or right internal jugular vein approaches; however, other peripheral (eg, antecubital vein) and central venous access sites can be used. Filters can be placed in veins other than the IVC to prevent thromboembolism (an off-label indication). Implant sites have included iliac veins, subclavian veins, superior vena cava, and IVC (suprarenal and infrarenal). This report provides quality improvement guidelines only for filter placement within the IVC because of the limited data available for implantation sites other than the IVC. The patient's clinical condition, the type of filter available, the available access sites, and the expertise of the treating physician should always be considered when the decision to place an IVC filter has been made.

IVC filters labeled as retrievable by the United States Food and Drug Administration are also labeled for permanent placement. Retrievable filters may be placed with the intent of either temporary or permanent filtration. Removal of retrievable IVC filters may be accomplished in those cases in which the indication was for prophylaxis and prevention of PE with temporary contraindication to anticoagulation. Filters placed with the intent of subsequent retrieval may be left in place permanently for any of several reasons (eg, continuing need for filtration, thrombus on the filter, inability to retrieve the filter). Data for the feasibility of filter retrieval vary widely among devices and centers. Filters that are not retrieved function as permanent filters.

Definitions

For the purpose of this guideline, the following definitions apply (24,25):

Permanent placement. Permanent placement is deployment in those situations in which lifelong protection against thromboembolic episodes is needed.

Temporary placement. Temporary placement is deployment in those situations in which time-limited protection against thromboembolic episodes is needed.

Procedural success. Procedural success is the deployment of a filter such that the filter is judged suitable for mechanical protection against PE.

Recurrent PE. Recurrent PE is PE that occurs after filter placement and is documented by pulmonary arteriography, cross-sectional imaging, or significant change in ventilation/perfusion lung scan indicative of recurrent PE, or at autopsy.

IVC thrombotic occlusion. IVC thrombotic occlusion is the presence of an occluding thrombus in the IVC after filter insertion and documented by ultrasound (US), CT, MR imaging, venography, or autopsy; this may be symptomatic or asymptomatic.

IVC penetration. IVC penetration is penetration of the vein wall by a filter strut or anchor device with transmural incorporation. For quality improvement reporting purposes, the definition of IVC penetration is filter strut or anchor devices extending more than 3 mm outside the wall of the IVC as demonstrated by CT or venography, or at autopsy. Acute penetration occurring during placement of the filter is considered an insertion problem (as detailed later).

Filter embolization. Filter embolization is postdeployment movement of the filter or its components to a distant anatomic site completely out of the target zone.

Filter movement. Filter movement is a change in filter position compared with its deployed position (cranial or caudal) of more than 2 cm as documented by plain radiography, CT, or venography.

Filter fracture. Filter fracture is any loss of a filter's structural integrity (ie, breakage or separation) documented by imaging or at autopsy.

Insertion problems. Insertion problems refer to malfunctions of the filter or deployment system such as incomplete filter opening, filter tilt more than 15° from the IVC axis (eg, non–self-centering filters), misplacement of filter outside the infrarenal IVC when the operator's intent is to place the filter in the infrarenal IVC (eg, when a portion of the filter is within one iliac vein), or prolapse of filter components. Filter malposition requiring surgical/endovascular removal is considered an insertion problem complication.

Access site thrombus. Access site thrombus refers to occlusive or nonocclusive thrombus developing at the venotomy site after filter insertion, and documented by US or other imaging.

Access site complications with clinical sequelae. Access site complications with clinical sequelae include arteriovenous fistula, hematoma, or bleeding requiring a transfusion, hospitalization (admission or extended stay), or further treatment.

Complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight; Appendix B). The complication rates and thresholds herein refer to major complications unless otherwise specified.

INDICATIONS

Therapeutic (Documented Thromboembolic Disease)

IVC filter placement has a therapeutic indication (ie, in cases of documented thromboembolic disease) in patients with evidence of PE or IVC, iliac, or femoropopliteal DVT and one or more of the following:

- Absolute or relative contraindication to anticoagulation;
- Complication of anticoagulation;
- Failure of anticoagulation;
- Recurrent PE despite adequate therapy;
- Inability to achieve/maintain adequate anticoagulation;
- Propagation/progression of DVT during therapeutic anticoagulation;
- Massive PE with residual DVT in a patient at risk for further PE;
- Free-floating iliofemoral or IVC thrombus; and

- Severe cardiopulmonary disease and DVT (eg, cor pulmonale with pulmonary hypertension) (24–31).

Prophylactic (No Current Thromboembolic Disease)

IVC filter placement has a prophylactic indication (ie, in cases without current thromboembolic disease) in the following settings:

- Severe trauma without documented PE or DVT;
- Closed head injury;
- Spinal cord injury;
- Multiple long-bone or pelvic fractures; and
- Patients at high risk (eg, immobilized or in an intensive care unit) (24–31).

Suprarenal Filter Placement

Suprarenal caval filter placement may be considered when any of the following situations exist in addition to the indications listed earlier.

1. Presence of IVC thrombus precluding placement of a filter in the infrarenal IVC;
2. Filter placement during pregnancy (suprarenal placement is also appropriate in women of childbearing age);
3. Thrombus extending above previously placed infrarenal filter;
4. Gonadal vein thrombosis;
5. Anatomic variants, eg, duplication of the IVC, low insertion of renal veins;
6. Significant extrinsic compression of the infrarenal IVC;
7. Intrinsic narrowing of the infrarenal IVC; and
8. Intraabdominal or pelvic mass in patients who will undergo surgery and in whom operative IVC mobilization is contemplated.

The IVC should be assessed with imaging before placement of a filter. The current preferred method is by vena cavography. Before filter selection and placement, the length and diameter of the suprarenal IVC should be assessed, the location and number of renal veins determined, the location and number of hepatic veins determined, the right atrium identified, IVC anomalies (eg, duplication) defined, and intrinsic IVC disease, such as preexisting thrombus or extrinsic compression, excluded. If available, previous imaging studies (eg, contrast-enhanced CT or MR imaging of the abdomen) may be used to evaluate the anatomy of the IVC (ie, size, patency, and anatomic variants). The anatomic considerations should be used in the final planning for filter placement and choice of device.

Filters Placed for Temporary Use and Possible Future Retrieval

Placement of filters for temporary use and possible future retrieval may be considered when any of the following situations exist in addition to the indications listed earlier.

1. PE and/or DVT and transient inability to anticoagulate;
2. Prophylactic prevention of PE in patients at high risk; and
3. The use of retrievable filters should also be considered in pediatric and young adult patients, as the long-term effects and durability of the devices are not precisely known. Currently, there are no filters specifically designed for use in children. The safety and efficacy of vena cava filters in children have not been firmly established. Case reports and series have described the placement and removal of filters in children, but their long-term effect is unclear (32).

The threshold for these indications is 95%. When fewer than 95% of procedures are performed for these indications, the process of patient selection should be reviewed according to institutional policy.

RELATIVE CONTRAINDICATIONS

Relative contraindications to IVC filter placement in this setting are (i) uncorrectable severe coagulopathy and (ii) bacteremia or untreated infection. Clinical judgment should be applied in these situations, weighing the theoretical risk of implant infection versus the risk of PE.

SPECIFICATIONS OF THE EXAMINATION

There are several technical requirements to ensure safe and successful filter placement procedures. These include adequate angiographic equipment and institutional facilities, physiologic monitoring equipment, and support personnel.

Equipment and Facilities for Filter Placement

The following are considered the minimum equipment requirements for performing vena cavograms and filter placement. In planning facilities for IVC placement, equipment and facilities more advanced than those outlined here may be desired to produce higher-quality studies with reduced risk and time of study.

The facility should include, at a minimum:

1. A high-resolution image receptor, preferably with a 28–40-cm field of view, and an imaging chain with standard angiographic filming capabilities including serial 14-inch film changers or (preferably) a digital imaging system with a minimum 1,024-image matrix. Digital angiographic systems are preferred, as they allow for reduced volumes of contrast material and reduced examination times. Images are acquired and stored on conventional film or digitally on computerized storage media. Imaging and image recording must be consistent with the "As Low As Reasonably Achievable" radiation safety guidelines. The use of cineradiography or small-field mobile image intensifiers is inappropriate for the routine recording of the vena cavogram and IVC placement, because these methods cause an unacceptably high patient and operator radiation dose. Use of last image-hold and pulsed fluoroscopy are recommended for dose reduction;
2. Adequate angiographic supplies such as catheters, guide wires, needles, and introducer sheaths;
3. An angiographic injector capable of varying injection volumes and rates with appropriate safety mechanisms to prevent overinjection;
4. An angiography suite that is large enough to allow easy transfer of the patient from the bed to the table and allow room for the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia equipment, and oxygen tanks. Ideally, there should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other technical staff in the room without contaminating the sterile conditions; and
5. An area within the institution appropriate for patient preparation before the procedure and for observation of patients after the procedure. This might be within the radiology department, a short-stay unit, a routine nursing unit, or a postanesthesia care unit. At this location, there should be personnel to provide care as outlined later in the Patient Care section, and there should be immediate access to emergency resuscitation equipment.

Physiologic Monitoring and Resuscitation Equipment

1. Equipment should be present in the procedure suite to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. For facilities that use moderate sedation, a pulse oximeter monitor should be available, as outlined in the Practice Guideline for Sedation/Analgesia (33).
2. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications and/or procedural complications. The equipment should be maintained and medications inventoried for drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

Support Personnel

Radiologic technologists properly trained in the use of the angiographic equipment should assist in performing and imaging the procedure. They

should demonstrate appropriate knowledge of patient positioning, angiographic image recording, angiographic contrast agent injectors, angiographic supplies including IVC filters, and the physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. The technologist should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment.

If the patient does not receive sedation for the procedure, one of the staff assisting the procedure should be assigned to periodically assess the patient's status. In cases in which moderate sedation is used in adults, light or moderate sedation is used in children, or the patient is critically ill, an experienced licensed provider should be present whose primary responsibility is monitoring the patient's vital signs, sedation state, and level of comfort/pain. This person should maintain a record of the patient's vital signs, the time and dose of medications given, and other pertinent information, as outlined in the Practice Guideline for Sedation/Analgesia (33).

Acute Care Support

Although surgical or other emergency treatment is needed infrequently for serious complications after filter placement procedures, there should be prompt access to surgical and interventional equipment and to specialists familiar with the management of patents with complications in the unlikely event of a life-threatening complication.

Patient Care

For additional information on patient care, see the Practice Guideline for Interventional Clinical Practice (34).

Preprocedure care. For elective filter placement, the following should be documented:

a. Clinically significant history, including indications for the procedure;
b. Clinically significant physical or diagnostic examination findings, including clinical or medical conditions that may necessitate specific care, such as preprocedure antibiotics and other measures;
c. Clinically indicated laboratory evaluation including, but not limited to, coagulation factors, creatinine, white blood cell count, and previously obtained cultures; and
d. Preprocedure documentation should conform to the requirements of the Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures (35).

Informed consent must be in compliance with all state laws and the ACR Practice Guideline on Informed Consent for Image-Guided Procedures (36).

For emergency procedures, a note should be written summarizing the indication for the study, the pertinent history and physical findings, if available, and the proposed procedure.

Procedural care. Adherence to the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery is required for procedures in non–operating room settings, including bedside procedures. "Time out" must be conducted in the location where the procedure will be done, just before starting the procedure and must:

- Involve the entire operative team;
- Use active communication; and
- Be briefly documented, such as in a checklist, and include at least:
  a. Correct patient identity;
  b. Correct side and site, if applicable;
  c. Agreement on the procedure to be done;
  d. Correct patient position; and
  e. Availability of correct implants and any special equipment or special requirements

The organization should have processes and systems in place for reconciling differences in staff responses during the time out.

All patients should have cardiac monitoring continuously during the procedure with intermittent blood pressure monitoring. A record of vital signs should be maintained.

All patients should have intravenous access for the administration of fluids and medications as needed.

If the patient is to receive sedation for the procedure, pulse oximetry should be used. A registered nurse or other appropriately trained personnel should be present, and his/her primary responsibility should be to monitor the patient. A record should be kept of medication doses and times of administration. The Practice Guideline for Sedation/Analgesia contains further information (33).

Postprocedure care. All patients should be in bed rest and observed in the initial postprocedure period. The duration of this period of bed rest will depend on the site and size of the venotomy and the patient's medical condition.

During the initial postprocedure period, skilled nurses or other appropriately trained personnel should periodically monitor the puncture site.

Initial ambulation of the patient must be carefully supervised. The puncture site stability and independent patient function and mobility must be assured.

The operating physician or a qualified designee should evaluate the patient after the procedure, and these findings should be summarized in a progress note. If conscious sedation was administered before and during the procedure, complete recovery from sedation must be documented. The physician or designee should be available for continuing care during hospitalization and after discharge. The designee may be another physician or a nurse. The Practice Guideline for Sedation/Analgesia contains further recommendations (33).

Selection Criteria for Short-term Observation

The duration of postprocedure observation must be individualized. IVC filter placement can be performed on some patients with a short period of postprocedure observation (< 6 h) before discharge to home; others require overnight care. Short-term observation should only be considered when all the following conditions can be met:

1. Those patients capable of independent ambulation before the procedure demonstrate stable independent ambulation after the procedure. Nonambulatory patients have adequate assistance after discharge to provide care as needed.
2. The patient is capable of following instructions and detecting changes in symptomatology. Alternatively, patients with impaired mental or neurologic status should have adequate assistance after discharge to provide care as needed.
3. The patient is provided with instructions on how to recognize potential complications and how to obtain medical assistance in the event of such complications. A responsible adult is also provided with information regarding recognition of potential complications and is available to transport the patient and be in attendance during the initial night after discharge.
4. The patient is free of concurrent serious medical illness that might contribute to a significantly increased risk of complication.
5. The patient has recovered from the effects of sedation.

Relative Contraindications to Short-term Observation

Several factors must be considered when determining the length of postprocedure skilled nursing care. Some of the relative contraindications to short-term observation are as follows:

1. Patients with significant risk of contrast media–associated nephrotoxicity that might be prevented by hospitalization and intravenous hydration.
2. Patients with coagulopathies or electrolyte abnormalities that require correction should be hospitalized until stable.
3. Insulin-dependent diabetic patients who have labile serum glucose levels in the periprocedural period should be hospitalized until in stable condition.
4. Complications occurring during or after IVC filter placement, including large hematoma, anuria, and persistent nausea and vomiting should prompt observation until symptoms resolve.

5. Patients who exhibit hemodynamic instability or significant dysrhythmia during or after the procedure should be hospitalized until in stable condition.
6. Patients who live alone.
7. Patients with concurrent serious medical illness that might contribute to a significantly increased risk of complication should be hospitalized until in stable condition.
8. Patients with impaired mental or neurologic status who do not have adequate assistance to provide care as needed should be hospitalized until appropriate assistance is available or no longer required.

The decision for short-term or longer-term postprocedure observation must be individualized, and a patient's care may vary from the aforementioned criteria for sound clinical reasons. The decision in each case must be made by the physician who performed the procedure and the referring physician after review of all pertinent data.

DOCUMENTATION

Reporting should be in accordance with the Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures (35).

RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This concept is known as As Low As Reasonably Achievable.

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with As Low As Reasonably Achievable, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index, or lateral width. The dose reduction devices that are available on imaging equipment should be active or manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR Technical Standard (ACR Resolution 17, adopted in 2006, revised in 2009, resolution 11).

QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading "Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Education" on the ACR Web page (*http://www.acr.org/guidelines*).

These data should be used in conjunction with the thresholds described in the subsequent section to assess filter placement procedural efficacy and complication rates, and to trigger institutional review when these thresholds are exceeded.

QUALITY IMPROVEMENT

Success Rates and Thresholds

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Thus indicator thresholds may be used to assess the efficacy of ongoing improvement programs. For the purpose of these guidelines, a threshold is a specific level of an indicator that should prompt a review. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a minimum threshold, or when complication rates exceed a maximum threshold, a review should be performed to determine causes and to implement changes, if necessary. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Therefore, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to higher or lower values to meet its own quality improvement program needs.

It is expected that the technical success for percutaneously placed IVC filters will be 97% or better in experienced hands. Therefore, the proposed threshold for review of technical failures should be 3%.

Participation by the radiologist in patient follow-up is an integral part and will increase the success rate of the procedure. Close follow-up, with monitoring and management of patients who have undergone placement of IVC filters is appropriate for the radiologist.

Table 1. Reported Rates and Thresholds for Complications (7,24,37–54)

Complication	Reported Rate (%)	Threshold (%)
Death (7)	0.12	<1
Filter embolization (24,37–49)	0.1	1
Deployment outside target area (50–52)	1–9	0
Access site thrombosis/ occlusion (53,54)	3–10	3

Table 2. Reported Incidences of Trackable Adverse Events (2,7,10,12,13,24,43,53,55–72)

Event	Reported Rate (%)
IVC penetration*(7,24,55–59)	0–41
Filter movement*(7,10,12,24,56,60–63)	0–18
Filter fracture (24,43)	2–10
Recurrent PE (24,56,61,53–65)	0.5–6
Access site thrombus, all types (7,53,64,65)	0–25
IVC occlusion (13,24,42,55,56,59,62,63,68)	2–30
Insertion problems (7,24,43,56,51–63,65,67,69,70)	5–23
Other complications (2,71,72)	1–15

* Clinically significant penetration and movement are believed to be rare. The rate of clinically significant penetration has been reported to be 0.4% (72), but is not precisely defined in the literature.

Complication Rates and Thresholds

Complications. Each currently available filter has been extensively studied as part of the Food and Drug Administration approval process. Few comparative studies have been completed to evaluate all filters in one project, and those that have done so have been retrospective analyses. Complication rates are highly variable depending on the filter being studied. For simplicity, these guidelines do not suggest threshold rates for each individual filter; rather, filtration devices are considered as a group (**Table 1**) (7,24,37–54).

Published rates for individual types of complications are highly dependent on patient selection and are, in some cases, based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs within a small patient volume (eg, early in a quality improvement program).

Other trackable events. Because an IVC filter may be implanted as a permanent device (if not retrieved) and can be used in relatively young patients, several other trackable parameters when observed are appropriate to record in a quality improvement program. The events listed in **Table 2** (2,7,10,12,13,24,43,53,55–72) may or may not be clinically significant in a particular patient. For this reason, thresholds for these events are not included in this document.

ACKNOWLEDGMENTS

Drew M. Caplin, MD, authored the first draft of this document and served as topic leader during the subsequent revisions of the draft. Wael E.A. Saad, MD, is chair of the SIR Standards of Practice Committee. Boris Nikolic, MD, MBA, is chair of the Revisions Subcommittee. Dr. Sanjoy Kundu served as SIR Standards Division Councilor during the development of this document and contributed to its content. All other authors are listed alphabetically. Other members of the Standards of Practice Committee and SIR who participated in the development of this clinical practice guideline are (listed alphabetically): John "Fritz" Angle, MD, Daniel B. Brown, MD, Danny Chan, MD, Sean R. Dariushia, MD, Jon C. Davidson, MD, B. Janne d'Othee, MD, MPH, Maxim Itkin, MD, Arshad Ahmed Khan, MD, Hyun S. Kim, MD, Gloria M. Martinez-Salazar, MD, Darren Postoak, MD, Tarun Sabharwal, MD, Cindy Kaiser Saiter, NP, Marc S. Schwartzberg, MD, Samir S. Shah, MD, Nasir H. Siddiqi, MD, Constantinos T. Sofocleous, MD, PhD, LeAnn Stokes, MD, Rajeev Suri, MD, Timothy L. Swan, MD, Patricia E. Thorpe, MD, Richard Towbin, MD, Aradhana Venkatesan, MD, Michael J. Wallace, MD, and Joan Wojak, MD.

REFERENCES

1. Prevention of venous thrombosis and pulmonary embolism. NIH Consensus Development. JAMA 1986; 256:744–749.
2. Clagett GP. Basic data related to venous thromboembolism. Ann Vasc Surg 1988; 2:402–405.
3. Dalen JE, Alpert JS. Natural history of pulmonary embolism. Prog Cardiovasc Dis 1975; 17:259–270.
4. Goldhaber SZ, Hennekens CH, Evans DA, Newton EC, Godleski JJ. Factors associated with correct antemortem diagnosis of major pulmonary embolism. Am J Med 1982; 73:822–826.
5. Glenny RW. Pulmonary embolism: complications of therapy. South Med J 1987; 80:1266–1276.
6. Silver D, Sabiston DC Jr. The role of vena caval interruption in the management of pulmonary embolism. Surgery 1975; 77:3–10.
7. Becker DM, Philbrick JT, Selby JB. Inferior vena cava filters. Indications, safety, effectiveness. Arch Intern Med 1992; 152:1985–1994.
8. Mobin-Uddin K, Smith PE, Martinez LO, et al. A vena caval filter for the prevention of pulmonary embolus. Surg Forum 1967; 18:209–211.
9. Asch MR. Initial experience in humans with a new retrievable inferior vena cava filter. Radiology 2002; 225:835–844.
10. Dorfman GS. Percutaneous inferior vena caval filters. Radiology 1990; 174:987–992.
11. Given M, Lyon S, Foster A, McGrath F, Lee M. Retrievable Gunther-Tulip filter: Experience in 41 Patients. Presented at the 2002 Annual Meeting of the Radiological Society of North America, December 6, 2002; Chicago, Illinois.
12. Grassi CJ. Inferior vena caval filters: analysis of five currently available devices. AJR Am J Roentgenol 1991; 156:813–821.
13. Greenfield LJ, DeLucia A III. Endovascular therapy of venous thromboembolic disease. Surg Clin North Am 1992; 72:969–989.
14. Hoppe H, Nutting CW, Smouse HR, et al. Günther Tulip filter retrievability multicenter study including CT follow-up: final report. J Vasc Interv Radiol 2006; 17:1017–1023.
15. Kinney TB. Update on inferior vena cava filters. J Vasc Interv Radiol 2003; 14:425–440.
16. Le Blanche AF, Benazzouz A, Reynaud P, et al. The VenaTech LP permanent caval filter: effectiveness and safety in the prevention of pulmonary embolism–a European multicenter study. J Vasc Interv Radiol 2008; 19:509–515.
17. Linsenmaier U, Rieger J, Schenk F, Rock C, Mangel E, Pfeifer KJ. Indications, management, and complications of temporary inferior vena cava filters. Cardiovasc Intervent Radiol 1998; 21:464–469.
18. Millward SF. Temporary and retrievable inferior vena cava filters: current status. J Vasc Interv Radiol 1998; 9:381–387.
19. Millward SF, Oliva VL, Bell SD, et al. Günther Tulip retrievable vena cava filter: results from the Registry of the Canadian Interventional Radiology Association. J Vasc Interv Radiol 2001; 12:1053–1058.
20. Oliva VL, Perreault P, Giroux MF, Bouchard L, Therasse E, Soulez G. Recovery G2 inferior vena cava filter: technical success and safety of retrieval. J Vasc Interv Radiol 2008; 19:884–889.
21. Savader SJ. Inferior vena cava filters. In: Savader SJ, Trerotola SO, eds. Venous interventional radiology with clinical perspectives. New York: Thieme, 1996; 367–399.
22. Yamagami T, Kato T, Iida S, Tanaka O, Nishimura T. Retrievable vena cava filter placement during treatment for deep venous thrombosis. Br J Radiol 2003; 76:712–718.
23. Ziegler JW, Dietrich GJ, Cohen SA, Sterling K, Duncan J, Samotowka M. PROOF trial: protection from pulmonary embolism with the OptEase filter. J Vasc Interv Radiol 2008; 19:1165–1170.
24. Ferris EJ, McCowan TC, Carver DK, McFarland DR. Percutaneous inferior vena caval filters: follow-up of seven designs in 320 patients. Radiology 1993; 188:851–856.
25. Ray CE Jr, Kaufman JA. Complications of inferior vena cava filters. Abdom Imaging 1996; 21:368–374.
26. Kalva SP, Chlapoutaki C, Wicky S, Greenfield AJ, Waltman AC, Athanasoulis CA. Suprarenal inferior vena cava filters: a 20-year single-center experience. J Vasc Interv Radiol 2008; 19:1041–1047.
27. Kaufman JA, Geller SC. When to use an inferior vena cava filter. AJR Am J Roentgenol 1995; 164:256–257.
28. Kaufman JA, Rundback JH, Kee ST, et al. Development of a research agenda for inferior vena cava filters: proceedings from a multidisciplinary research consensus panel. J Vasc Interv Radiol 2009; 20:697–707.
29. Norris CS, Greenfield LJ, Herrmann JB. Free-floating iliofemoral thrombus. A risk of pulmonary embolism. Arch Surg 1985; 120:806–808.
30. Rutherford RB. Prophylactic indications for vena cava filters: critical appraisal. Semin Vasc Surg 2005; 18:158–165.
31. Vaiji K. Vascular and interventional radiology. Philadelphia: WB Saunders, 1999.
32. Chaudry G, Padua HM, Alomari AI. The use of inferior vena cava filters in young children. J Vasc Interv Radiol 2008; 19:1103–1106.
33. Practice Guideline for Sedation/Analgesia. Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/iv.aspx.
34. Practice Guideline for Interventional Clinical Practice. Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/iv.aspx.
35. Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures. Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/iv.aspx.
36. ACR Practice Guideline on Informed Consent for Image-Guided Procedures. Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/iv.aspx.
37. Akins CW, Thurer RL, Waltman AC, Margolies MN, Schneider RC. A misplaced caval filter: its removal from the heart without cardiopulmonary bypass. Arch Surg 1980; 115:1133.
38. Bach JR, Zaneuski R, Lee H. Cardiac arrhythmias from a malpositioned Greenfield filter in a traumatic quadriplegic. Am J Phys Med Rehabil 1990; 69:251–253.
39. Castaneda F, Herrera M, Cragg AH, et al. Migration of a Kimray-Greenfield filter to the right ventricle. Radiology 1983; 149:690.
40. Friedell ML, Goldenkranz RJ, Parsonnet V, et al. Migration of a Greenfield filter to the pulmonary artery: a case report. J Vasc Surg 1986; 3:929–931.
41. LaPlante JS, Contractor FM, Kiproff PM, Khoury MB. Migration of the Simon nitinol vena cava filter to the chest. AJR Am J Roentgenol 1993; 160:385–386.

42. Loesberg A, Taylor FC, Awh MH. Dislodgment of inferior vena caval filters during "blind" insertion of central venous catheters. AJR Am J Roentgenol 1993; 161:637–638.
43. Magnant JG, Walsh DB, Juravsky LI, Cronenwett JL. Current use of inferior vena cava filters. J Vasc Surg 1992; 16:701–706.
44. Puram B, Maley TJ, White NM, Rotman HH, Miller G. Acute myocardial infarction resulting from the migration of a Greenfield filter. Chest 1990; 98:1510–1511.
45. Simon M. Vena cava filters: prevalent misconceptions. J Vasc Interv Radiol 1999; 10:1021–1024.
46. Urbaneja A, Fontaine AB, Bruckner M, Spigos DG. Evulsion of a Vena Tech filter during insertion of a central venous catheter. J Vasc Interv Radiol 1994; 5:783–785.
47. Villard J, Detry L, Clermont A, Pinet F. Eight cases of Greenfield filters in the right heart cavities. Their surgical treatment. Ann Radiol 1987; 30:102–104.
48. Athanasoulis CA, Kaufman JA, Halpern EF, Waltman AC, Geller SC, Fan CM. Inferior vena caval filters: review of a 26-year single-center clinical experience. Radiology 2000; 216:54–66.
49. Hammond CJ, Bakshi DR, Currie RJ, et al. Audit of the use of IVC filters in the UK: experience from three centres over 12 years. Clin Radiol 2009; 64:502–510.
50. Baglin TP, Brush J, Streiff M. Guidelines on use of vena cava filters. Br J Haematol 2006; 134:590–595.
51. Cipolla J, Wegner NS, Sharma R, et al. Complications of vena cava filters: A comprehensive clinical review. OPUS 12 Scientist 2008; 2:11–23.
52. Savin MA, Panicker HK, Sadiq S, Albeer YA, Olson RE. Placement of vena cava filters: factors affecting technical success and immediate complications. AJR Am J Roentgenol 2002; 179:597–602.
53. Hicks ME, Middleton WD, Picus D, Darcy MD, Kleinhoffer MA. Prevalence of local venous thrombosis after transfemoral placement of a Bird's Nest vena caval filter. J Vasc Interv Radiol 1990; 1:63–68.
54. Luanow E, Kandarpa K, Chopra, et al. Bleeding complications in patients undergoing percutaneous vena cava filter placement using new low profile introduction systems. Presented at the American Roentgen Ray Annual Meeting; April 27, 1993; San Francisco, California.
55. Greenfield LJ, Cho KJ, Proctor M, et al. Results of a multicenter study of the modified hook-titanium Greenfield filter. J Vasc Surg 1991; 14: 253–257.
56. Greenfield LJ, Proctor MC. Vena caval filter use in patients with sepsis: results in 175 patients. Arch Surg 2003; 138:1245–1248.
57. Lang W, Schweiger H, Hofmann-Preiss K. Results of long-term venacavography study after placement of a Greenfield vena caval filter. J Cardiovasc Surg (Torino) 1992; 33:573–578.
58. Murphy TP, Dorfman GS, Yedlicka JW, et al. LGM vena cava filter: objective evaluation of early results. J Vasc Interv Radiol 1991; 2:107–115.
59. Ricco JB, Crochet D, Sebilotte P, et al. Percutaneous transvenous caval interruption with the "LGM" filter: early results of a multicenter trial. Ann Vasc Surg 1988; 2:242–247.
60. Athanasoulis CA. Complications of vena cava filters. Radiology 1993; 188:614–615.
61. Crochet DP, Stora O, Ferry D, et al. Vena Tech-LGM filter: long-term results of a prospective study. Radiology 1993; 188:857–860.
62. Hye RJ, Mitchell AT, Dory CE, Freischlag JA, Roberts AC. Analysis of the transition to percutaneous placement of Greenfield filters. Arch Surg 1990; 125:1550–1553.
63. Millward SF, Peterson RA, Moher D, et al. LGM (Vena Tech) vena caval filter: experience at a single institution. J Vasc Interv Radiol 1994; 5:351–356.
64. Greenfield LJ, Proctor MC. Twenty-year clinical experience with the Greenfield filter. Cardiovasc Surg 1995; 3:199–205.
65. Simon M, Athanasoulis CA, Kim D, et al. Simon nitinol inferior vena cava filter: initial clinical experience. Work in progress. Radiology 1989; 172:99–103.
66. Molgaard CP, Yucel EK, Geller SC, Knox TA, Waltman AC. Access-site thrombosis after placement of inferior vena cava filters with 12-14-F delivery sheaths. Radiology 1992; 185:257–261.
67. Vesely TM. Technical problems and complications associated with inferior vena cava filters. Semin Interven Radiol 1994; 11:121–133.
68. McCowan TC, Ferris EJ, Carver DK, Molpus WM. Complications of the nitinol vena caval filter. J Vasc Interv Radiol 1992; 3:401–408.
69. Moore BS, Valji K, Roberts AC, Bookstein JJ. Transcatheter manipulation of asymmetrically opened titanium Greenfield filters. J Vasc Interv Radiol 1993; 4:687–690.
70. Sweeney TJ, Van Aman ME. Deployment problems with the titanium Greenfield filter. J Vasc Interv Radiol 1993; 4:691–694.
71. Teitelbaum GP, Jones DL, van Breda A, et al. Vena caval filter splaying: potential complication of use of the titanium Greenfield filter. Radiology 1989; 173:809–814.
72. Stawicki SP, Sims CA, Sharma R, et al. Vena cava filters: a synopsis of complications and related topics. J Vasc Access 2008; 9:102–110.

APPENDIX A: SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

A. Require no therapy, result in no consequence.
B. Require nominal therapy, result in no consequence; includes overnight admission (≥ 23 h) for observation only.

Major Complications

C. Require therapy, minor hospitalization (≥ 24 h but < 48 h).
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 h).
E. Result in permanent adverse sequelae.
F. Result in death.

APPENDIX B: CONSENSUS METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee members' practices, and, when available, the SIR HI-IQ System national database.

Consensus on statements in this document was obtained utilizing a modified Delphi technique (1,2).

The Committee was unable to reach consensus on the following:

1. Indication, efficacy, or complication threshold.
2. Indication, efficacy, or complication threshold.

REFERENCES

1. Fink A, Kosefcoff J, Chassin M, Brook RH. Consensus methods: characteristics and guidelines for use. Am J Public Health 1984; 74:979–983.
2. Leape LL, Hilborne LH, Park RE, et al. The appropriateness of use of coronary artery bypass graft surgery in New York State. JAMA 1993; 269:753–760.

SIR DISCLAIMER

SIR Disclaimer The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.